Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–382]

Schedules of Controlled Substances: Temporary Placement of Three Synthetic Phenethylamines Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of Intent.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily schedule three synthetic phenethylamines into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) [hereinafter 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe]. This action is based on a finding by the Deputy Administrator that the placement of these synthetic phenethylamines into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will be published in the **Federal Register** and may not be issued prior to November 12, 2013. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to Schedule I substances under the CSA on the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of these synthetic phenethylamines.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355, for the substance. 21 U.S.C. 811(h)(1). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, 0.104.

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.[1] As 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are not currently listed in any schedule under the CSA, the DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. Any comments submitted by the Assistant Secretary in response to this notification shall be taken into consideration before a final order is published. 21 U.S.C. 811(h)(4).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)–(6). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe indicate that these three synthetic phenethylamines have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Synthetic Phenethylamines

The 2-methoxybenzyl series of 2C phenethylamine substances, such as 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe, has been developed over the last 10 years for use in mapping and investigating the serotonin receptors in the mammalian brain. 25I-NBOMe and 25B-NBOMe were first described by legitimate research laboratories in 2003. Subsequent studies involving these two substances appeared in the scientific literature starting in 2006. 25C-NBOMe first appeared in the scientific literature in 2011. No approved medical use has been identified for these synthetic phenethylamines, nor have they been approved by the FDA for human consumption. Synthetic 2C phenethylamine substances, of which 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are representative, are so-termed for the two-carbon ethylene

[1] Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Notice of Intent, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.'' As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

group between the phenyl ring and the amino group of the phenethylamine and are substituted with methoxy groups at the 2 and 5 positions of the phenyl ring. Numerous blotter papers and food items have been analyzed, and combinations of one or more of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been identified as adulterants. Bulk quantities of these substances have been encountered as powders and liquid solutions.

From November 2011 through June 2013, according to the System to Retrieve Information from Drug Evidence [2] (STRIDE) data, there are 54 exhibits involving 27 cases for 25I-NBOMe; 27 exhibits involving 12 cases for 25C-NBOMe; and 3 exhibits involving 3 cases for 25B-NBOMe. From June 2011 through March 2013, the National Forensic Laboratory Information System [3] (NFLIS) registered 689 reports containing these synthetic phenethylamines (25I-NBOMe-582 reports; 25C-NBOMe-94 reports; 25B-NBOMe-13 reports) across 33 states. No instances involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe were reported in NFLIS prior to June 2011.

Factor 4. History and Current Pattern of Abuse

One or more 2-methoxybenzyl analogues of the 2C compounds described here have been available over the Internet since 2010. The first identified domestic law enforcement encounter with 25I-NBOMe occurred in June 2011 in Milwaukee, Wisconsin.

Information from published studies and law enforcement reports, supplemented with discussions on Internet Web sites and personal communications, document abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe by nasal insufflation of powders, intravenous injection or nasal absorption of liquid solutions, sublingual or buccal administration of blotter papers, and consumption of food items laced with these substances. These sources also report that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are often purported to be Schedule I hallucinogens like lysergic acid diethylamide (LSD). Reports document that the abuse of these substances can cause severe toxic reactions, including death.

According to United States Customs and Border Protection data, bulk quantities of powdered 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been seized from shipments originating overseas, particularly from Asia. Given the relatively small quantity of these substances predicted to produce a hallucinogenic effect in humans, single seizures of these substances are capable of producing hundreds of thousands to millions of dosage units. Large seizures of these substances prepared on blotter papers have also been reported. Abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe has been characterized with acute public health and safety issues domestically and abroad. In response, a number of states and foreign governments have controlled these substances.

Factor 5. Scope, Duration and Significance of Abuse

According to forensic laboratory reports, the first law enforcement encounter with 25I-NBOMe in the United States occurred in June 2011. According to NFLIS, 689 exhibits involving 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe were submitted to forensic laboratories between June 2011 and March 2013 from a number of states including Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Iowa, Indiana, Illinois, Kansas, Kentucky, Louisiana, Maryland, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, North Dakota, Nebraska, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. The number of reports submitted to NFLIS involving 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe has increased in each of the last five quarters where data is available. According to STRIDE, there are 84 records that identify 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in evidence submitted to DEA laboratories between November 2011 and June 2013.

Factor 6. What, if Any, Risk There Is to the Public Health

In 2012 and 2013, emergency department physicians and toxicologists published and presented numerous case reports of patients treated for exposure to 25I-NBOMe. The adverse health effects reported include tachycardia, hypertension, agitation, aggression, visual and auditory hallucinations, seizures, hyperpyrexia, clonus, elevated white cell count, elevated creatine kinase, metabolic acidosis, rhabdomyolysis, and acute kidney injury.

Medical examiner and postmortem toxicology reports from 11 states implicate some combination of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in the death of at least 14 individuals. These reports suggest that 11 individuals died of acute toxicity, and 3 individuals died of unpredictable or violent behavior due to 25I-NBOMe toxicity. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have each been detected in postmortem blood toxicology for cases of acute toxicity.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses of these substances in the United States and possible deadly drug interactions between 25I-NBOMe and FDA approved medications have been noted.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

Based on the above data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these synthetic phenethylamines in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe indicate that these three synthetic phenethylamines have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator through a letter dated September 3, 2013, notified the Assistant Secretary of the intention to temporarily place these three synthetic phenethylamines in Schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is

[2] STRIDE includes data on analyzed samples from DEA laboratories.

[3] NFLIS is a database that collects scientifically verified data on analyzed samples in state and local forensic laboratories.

necessary to temporarily schedule three synthetic phenethylamines, 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36), in Schedule I of the CSA, and finds that placement of these synthetic phenethylamines into Schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic phenethylamines into Schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the permanent or regular scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importation, exportation, research, and conduct of instructional activities of a Schedule I controlled substance under the CSA.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of a proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Deputy Administrator will be taking into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 201(h) of the CSA, 21 U.S.C. 811(h), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, Appendix to Subpart R), the Deputy Administrator hereby intends to order that 21 CFR Part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding new paragraphs (h)(12), (13), and (14) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(12) 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers— 7538 (Other names: 25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)

(13) 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl) ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers—7537 (Other names: 25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)

(14) 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl) ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers—7536 (Other names: 25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)

Dated: October 4, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–24432 Filed 10–9–13; 8:45 am]

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